Remarks

Claims 1-18 were previously pending in the subject application. By this Amendment, claims 1-3, 7, 8, 10, and 11 have been amended, claim 6 has been canceled, and new claims 19 and 20 have been added. Additionally, thc specification has been amended. Support for the amendments and new claims can be found throughout the original specification (see, for example; page 3, line 26 through page 5, line 12; page 5, line 23 through page 6, line 2; page 11, line 7 through page 13, line 8; original claims 4 and 6; and Figure 2-4). Upon entry of this Amendment, claims 1-5 and 7-20 will be before the Examiner for consideration.

The amendments to the claim have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendment should not be construed as an indication of the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the amendments and remarks set forth herein, is earnestly solicited.

Claims 1-18 have been rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The applicants respectfully request reconsideration.

The Action indicates that the specification does not describe the term "mean diameter." Though the applicants do not necessarily agree, by this Amendment, the claims have been amended to remove the term "mean"; the claims now recite that the diameter of the channel is greater than the path. The applicants respectfully submit that a skilled artisan would readily understand this term as referring to the diameter defined by a cross-section of the channel.

Additionally, the Action indicates that the turning points, the curves, and the relationships between these components are not clear. The Action also suggests amending the claims and the specification to clarify these points. By this Amendment, independent claims 1 and 11 have been amended to recite that the channel has opposing curves having turning points "where the flow direction of the fluid stream flowing through the channel inflects to an opposite curvature," and also that the diameter of the channel is greater than "the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature."

Moreover, the specification has also been amended to more clearly convey the structure of the channel of the subject invention. The definitions of the turning points and the curves have been clarified. That is, a turning point is to be understood in a mathematical way as an inflection point along the channel. A skilled artisan would readily understand the term inflection point (http://en.wikipedia.org/wiki/Inflection_point; a copy of this page is attached hereto for the Examiner's convenience). The applicants submit that no new matter has been added by the amendments to the specification since these features of the claimed invention can be plainly seen in the original Figures 2-4.

Furthermore, the Action states that it is unclear how the diameter of the channel can be greater than the path between two turning points. However, the applicants wish to emphasize that this limitation is not recited in the claims (as previously presented or as currently presented). Instead, the claimed invention requires that "the diameter of the channel is greater than the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature" (emphasis added). That is, the diameter of the channel is greater than the path covered by an analyte molecule by diffusion as it travels through the channel from one turning point located at the beginning of a eurve to the turning point located at the beginning of the next curve that has the same curvature as the first curve. Since the curves alternate in curvature, the next curve having the same curvature would not be the very next curve (of any curvature) seen by the analyte molecule, but rather the one after that.

Thus, the path which the diameter of the channel must be greater than is the path which an analyte molecule covers through diffusion as it travels between sequential turning points located at the beginning of sequential curves that each have the same curvature. As is understood in the art and described in the subject specification (see, for example; page 4, line 27 through page 5, line 4; discussion of "racetrack effect"), as an analyte molecule travels through a channel in a separation column, the molecule diffuses in a radial direction from one side of the channel toward the diametrically opposite side of the channel (i.e. approximately perpendicular to the direction of the fluid flow). This distance covered by the molecule in a radial direction of the channel, as it moves

from one turning point to the next turning point that inflects to the same curvature, is the path which the mean diameter must be greater than.

As the Examiner is aware, "the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." MPEP §2164.01. The applicants submit that a skilled artisan could readily make and use the claimed invention based on the disclosure in the specification.

Thus, one of ordinary skill in the art would be able to make and use the claimed invention based on the subject specification without undue experimentation. Accordingly, the applieants respectfully request reconsideration and withdrawal of the rejection under §112, first paragraph.

Claims 1-18 have been rejected under 35 U.S.C. §102(a) and (b) as being anticipated by Lehmann *et al.* (IDS: Sensor 2003 Proceedings, 157-161). The applicants respectfully traverse these grounds of rejection because the Lehmann *et al.* reference does not teach each and every element of the claimed invention.

The claimed invention requires that "the diameter of the channel is greater than the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature." Lehmann *et al.*, on the other hand, fail to disclose, or even contemplate, this novel and advantageous feature of the subjeet invention.

The applicant would like to emphasize that the claimed invention addresses the problem arising from the "racetrack effect" in separation columns having curves, as discussed in the subject specification (see, for example; the paragraph bridging pages 1 and 2). Generally, molecules following an "inner path" of a curve follow a shorter path then those molecules following an "outer path" of the samc curve. The molecules can be separated from each other leading to a spread in the sample flowing through the separation column. This can adversely affect the quality of the analysis since the separation of the molecules in the separation column should only depend on their molecular weight and not on the path they flow along in the column.

The applicants have discovered that the measure of only providing curves in alternate directions in a separation column is not sufficient to significantly decrease the spread of a sample

within the column. The applicants have also discovered that inhibiting diffusion of the analyte molecules from one side of the column to the other side can help address this problem. Thus, the subject invention addresses the "racetrack effect" problem by providing a channel in which "the diameter of the channel is greater than the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature."

The separation column of Lehmann *et al.* fails to teach, or even suggest, this novel and advantageous feature of the subject invention and instead suffers from the same problems of the "racetrack effect" as those of the related art.

As the Examiner is aware, it is a basic premise of patent law that in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). As discussed above, Lehmann *et al.* do not disclose certain advantageous aspects of the claimed invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection based on Lehmann *et al.*

Claims 1-18 have been rejected under 35 U.S.C. §102 as being unpatentable over the Applicant's Admission of Prior Art (Fig. 1; and page 10, line 11 – page 11, line 6.). The applicants respectfully traverse this ground for rejection.

The claimed invention requires that "the diameter of the channel is greater than the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature." In the separation column disclosed at page 10, line 11 through page 11, line 6 and depicted in Figure 1, the channel diameter "is <u>smaller</u> than the path which the analyte molecule covers through diffusion on its way between two turning points 29, 30" (emphasis added). This is in direct contrast to the separation column recited in the claims and leads to defocusing of the analyte package and other problems arising from the "racetrack effect."

As discussed above, it is a basic premise of patent law that in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic, supra.* The separation column disclosed in Figure 1 fails to teach certain advantageous elements of the claimed invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection based on AAPA.

Furthermore, though it is not required to overcome the rejections under §102, the applicants respectfully submit that a skilled artisan would not have had a reason to modify the separation column of Lehmann *et al.* or AAPA to arrive at the claimed invention.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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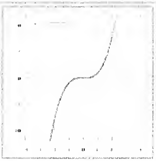
LCF/la

Attachment: Inflection Point Wikipedia page

Inflection point

From Wikipedia, the free encyclopedia



Plot of $y = x^3$ with inflection point of (0,0), also a saddle point.

In differential calculus, an **inflection point**, or **point of inflection** (or **inflexion**) is a point on a curve at which the curvature changes sign. The curve change from being concave upwards (positive curvature) to concave downwards (negative curvature), or vice versa. If one imagines driving a vehicle along a winding road, it is a point at which the steering-wheel is momentarily "straight" when being turned from left to right or vice versa.

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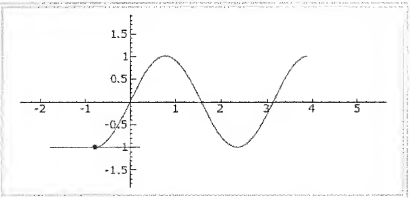
Equivalent forms

The following are all equivalent to the above definition:

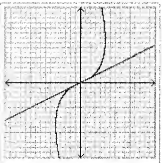
- a point on a curve at which the second derivative changes sign. This is very similar to the previous definition, since the sign of the curvature is always the same as the sign of the second derivative, but note that the curvature is not the same as the second derivative.

- a point (x,y) on a function, $f(x)$, at which the first derivative, $f'(x)$, is at an extremum, i.e. a minimum or maximum. (This is not the same as saying that y is at an extremum).

- a point on a curve at which the tangent crosses the curve at that point.



Plot of $f(x) = \sin(2x)$ from $-\pi / 4$ to $5 * \pi / 4$; note f's second derivative is $f''(x) = -4 * \sin(2x)$. Tangent is blue where curve is concave up (above its own tangent), green where concave down



Plot of $y = x^3$, rotated, with tangent line at inflection point of (0,0).

A necessary but not

(below its tangent), and red at inflection points: 0, $\pi / 2$ and π

sufficient condition

Note that since the first derivative is at an extremum, it follows that the second derivative, $f''(x)$, is equal to zero, but the latter condition does not provide a sufficient definition of a point of inflection. One also needs the lowest-order non-zero derivative to be of odd order (third, fifth, etc.). If the lowest-order non-zero derivative is of even order, the point is not a point of inflection. (An example of such a function is $y = x^4$).

It follows from the definition that the sign of $f'(x)$ on either side of the point (x,y) must be the same. If this is positive, the point is a *rising point of inflection*; if it is negative, the point is a *falling point of inflection*.

Categorization of points of inflection

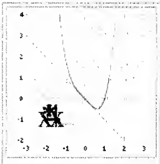
Points of inflection can also be categorised according to whether $f'(x)$ is zero or not zero.

- if $f'(x)$ is zero, the point is a *stationary point of inflection*, also known as a saddle-point
- if $f'(x)$ is not zero, the point is a *non-stationary point of inflection*

An example of a saddle point is the point (0,0) on the graph $y=x^3$. The tangent is the x-axis, which cuts the graph at this point.

A non-stationary point of inflection can be visualised if the graph $y=x^3$ is rotated slightly about the origin. The tangent at the origin still cuts the graph in two, but its gradient is non-zero.

Note that an inflection point is also called an *ogee*, although this term is sometimes applied to the entire curve which contains an inflection point.



Plot of $y = x^4 - x$ with tangent line at non-inflection point of (0,0).

Asymptotic functions

It is worthy to note that some functions change concavity without having points of inflection. Take, for example, the function $2x^2 / (x^2 - 1)$. It is concave up when $|x| > 1$ and concave down when $|x| < 1$. However, it has no points of inflection because 1 and -1 are not in the domain of the function.

See also

- Critical point (mathematics)

External links

- Inflection Points of Fourth Degree Polynomials
- Mathematical Explanation of Inflection Points

Categories: Differential calculus | Curves | Analytic geometry
Hidden categories: Articles lacking sources from January 2008 | All articles lacking sources